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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,731	Applicant(s) DENG ET AL.	
	Examiner Nathan W. Schlientz	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 14-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/18/09 and 3/26/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-10 and 14-28 are pending in the present application and are examined herein on the merits for patentability. No claim is allowed at this time.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 18 November 2009 and 26 March 2010 were filed after the mailing date of the non-final Office action on 30 September 2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 1-10 and 14-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Podhajny (US 2003/0091767 A1) in view of Sugiura et al. (US 5,296,238).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Podhajny teaches that it was known to prepare antibiotic films by admixing zeolites and a variety of polymer materials in a usual manner and forming the films by any known method such as casting, extrusion, and drawing methods ([0008]). Podhajny further teaches that non-leeching, long acting, anti-microbial coatings, which kill microorganisms on contact are known ([0009]). Podhajny teaches a method of applying an anti-microbial treatment to the surface of a packaging material, wherein the method includes providing a substantially inert dispersion comprising a polymer and anti-microbial zeolites, preferably a zeolite containing silver ions, printing the dispersion onto the packaging material surface and drying the dispersion to form a coating layer having the polymer and zeolites on at least a portion of the exposed surface thereof ([0011]). The zeolites comprise from about 0.5% to about 10% by weight of the dispersion and preferably have a particle size of between about 2 and about 5 μm ([0012]). The coating layer includes a polymeric material and zeolites containing silver ions, which are present on at least a portion of the exposed surface of the coating layer ([0013]). Podhajny teaches a method for rendering a nylon, or polystyrene film anti-

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microbial or more resistant to bacteria by applying a water-based dispersion to the film ([0014]).

Podhajny teaches food packaging films suitable for use in their invention include polymeric films such as blown film, oriented film, stretch and shrink film, heat shrinkable bags and food casings. Suitable films include regenerated cellulose and thermoplastic stretch or shrink films, and may be monolayer or multilayer films. Shrink films are preferably formed into heat shrinkable, biaxially oriented bags. Plastics such as homopolymers or copolymers of polyolefin's, e.g. polypropylene, polyethylene, or polyamides, polyethylene terephthalate, polyvinylidene chloride copolymers or ethylene-vinyl acetate copolymers may also be used to form the food-contacting films ([0052]).

Podhajny claims a packaging material having anti-microbial properties on at least one surface thereof, comprising an anti-microbial coating layer printed on the surface of said packaging material, said coating layer comprising an exposed surface containing a polymer and zeolites containing anti-microbial metal ions, said zeolites having a particle size of between about 2 and about 5 μm , a pore size of between about 3 and about 5 Å, and comprising from about 0.1 to about 5% by weight of said coating layer (claim 23). The packaging material of claim 23, wherein the anti-microbial metal ion is a silver ion (claim 24); the zeolites comprise from about 0.1 to about 5% by weight of the coating layer (claim 25); the polymer is selected from the group consisting of polyamides, acrylics, polyvinyl chloride, methyl methacrylates, polyurethanes, ethyl cellulose, polyvinylbutyral, polyketones, and nitrocelluloses (claim 27); the polymer is polyester

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(claim 28) or sulfonated polyester (claim 29); and the coating layer has a thickness of about 2-8 μm (claim 31).

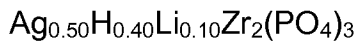
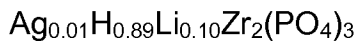
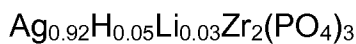
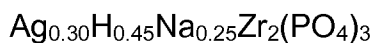
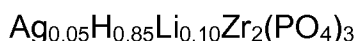
With regard to the heat-seal strength or barrier to water vapor or oxygen, the haze, the gloss and the degree of shrinkage, the compositions according to Podhajny are prepared with the same polymeric substrate, polymeric coating layer and anti-microbial compound with the same layer thickness. Therefore, in the absence of evidence to the contrary, the films according to Podhajny inherently possess the same heat-seal strength or barrier to water vapor or oxygen, haze, gloss and degree of shrinkage as the instantly claimed polymeric films. The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

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Podhanjy does not teach anti-microbial compounds comprising phosphate containing an anti-microbial metal ion, such as silver. However, Sugiura et al. teach a microbicide which contains, as an active ingredient, a specific phosphate containing a metal ion having antibacterial, antifungal or antialgal activity such as silver, copper, zinc, tin, mercury, lead, iron, cobalt, nickel, manganese, arsenic, antimony, bismuth, barium, cadmium or chromium ion, and the microbicide can be used as antimicrobial compositions which comprise the microbicide mixed with various binders or as antimicrobial shaped products which comprise the microbicide supported on carriers such as fibers, films, papers, and plastics (col. 1, ln. 4-14). Silver is the especially preferred metal from the points of stability and antimicrobial activity (col. 3, ln. 1-2). Specific examples of phosphate antimicrobials include (col. 3, ln. 14-53; and Table 5):



Sugiura et al. teach preparation of the above microbicides wherein after completion of washing with water, the residue was subjected to classification using a screen to collect fine particles of 1.0 μm or less (col. 10, ln. 31-34). The microbicide can be used in various forms such as powder-containing films (col. 5, ln. 21-35), wherein the

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films include food-packaging films and medical films (col. 5, ln. 44-45). Evaluation test 1 teaches adding 2 parts by weight microbicide to 100 parts by weight polyethylene terephthalate in a solvent, injection molding at 270 °C to make a product (col. 8, ln. 5-12). Sugiura et al. further teach fine powders comprising silver wherein the average particle size is 1.0 or 1.1 μm (col. 13, ln. 6-14). Sugiura et al. claim a method of inhibiting the growth of microorganisms on a surface comprising coating or impregnating said surface with an antimicrobially effective amount of the microbicide (claim 6).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to incorporate the anti-microbial phosphate containing an anti-microbial metal ion according to Sugiura et al. into the anti-microbial films according to Podhanjy. One of ordinary skill in the art would have a reasonable expectation of success because Sugiura et al. teach incorporation of the phosphate containing silver into films wherein the resulting films are antimicrobial.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on page 8 that the only apparent overlap of polymers disclosed by Podhajny and the instant application are the “acrylics” group, and not all acrylic polymers are heat-sealable and/or provide a barrier to water vapor and/or oxygen. Applicants further argue that acrylic polymers satisfying these conditions are a small subset of all acrylic polymers, and there is no disclosure in Podhajny of this small subset of acrylic polymers. However, Podhajny teaches that adhering their antimicrobial dispersion to polyethylene film, paper, nylon, etc., wherein the films to which an antimicrobial dried coating layer of zeolites may be added, may be alcohol based and heat sealable, and are easily rendered non-fogging ([0030]-[0032]). Therefore, one of ordinary skill in the art would be motivated to use a heat-sealable coating layer. The instant specification states that suitable heat-sealable or sealant coatings are well-known in the art (pg. 11, ln. 4-13). Therefore, it would be well within the purview of one of ordinary skill in the art to select the appropriate heat-sealable coating for use in Podhajny.

2. Claims 1-10 and 14-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konagaya et al. (EP 0 846 418 A1) in view of Sugiura et al. (US 5,296,238).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Konagaya et al. teach an inorganic and/or organic antibacterial agent and a hydrophilic substance used in combination to produce an antibacterial composition.

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High antibacterial moldings can be obtained by laminating the antibacterial composition on an inorganic or organic substrate (Abstract). Konagaya et al. teach that the inorganic antibacterial agent is an inorganic compound which carries the particles and/or ions of at least one metal selected from the group consisting of silver, zinc and copper (claim 3). An antibacterial laminate is prepared by laminating the antibacterial composition comprising the metal particles and/or ions on at least one surface of an inorganic or organic substrate (claim 13), wherein the organic substrate is a molded product, such as a film or sheet (claim 17), prepared from a thermoplastic resin (claim 15) selected from the group consisting of PVC, polyvinylidene chloride, PE, PP, polyamide, polystyrene, polyacrylonitrile, polyester and polyurethane (claim 16).

Konagaya et al. further teach the thermoplastic or thermosetting resin including PE, PP, PVC, PVA, nylon, polyethylene terephthalate, polycarbonate, polystyrene, polyurethane, etc. (pg. 9, ln. 28-34). A transparent PET film having a dried thickness of 0.3 μm (Example 23). The average diameter of primary particles is 0.01 to 5 μm , and preferably present at 5% by weight or less (pg. 9, ln. 10-11). The antibacterial films or sheets are suitable for use as a film or sheet for wall papers, wrapping foods, a shrink film, a shrink label, a base film for magnetic tape, a film for wrapping semi-conducting or electronic materials, magnetic card, OHP, a support for photographic materials, heat-sensitive papers, etc. (pg. 9, ln. 48-51).

With regard to the heat-seal strength or barrier to water vapor or oxygen, the haze, the gloss and the degree of shrinkage, the compositions according to Konagaya et al. are prepared with the same polymeric substrate, polymeric coating layer and anti-

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microbial compound with the same layer thickness. Therefore, in the absence of evidence to the contrary, the films according to Konagaya et al. inherently possess the same heat-seal strength or barrier to water vapor or oxygen, haze, gloss and degree of shrinkage as the instantly claimed polymeric films. The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

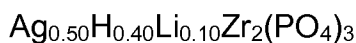
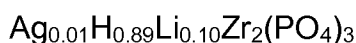
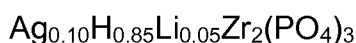
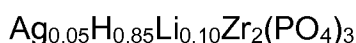
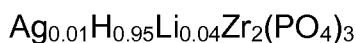
Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Konagaya et al. do not teach anti-microbial compounds comprising phosphate containing an anti-microbial metal ion, such as silver. However, Sugiura et al. teach a microbicide which contains, as an active ingredient, a specific phosphate containing a metal ion having antibacterial, antifungal or antialgal activity such as silver, copper, zinc, tin, mercury, lead, iron, cobalt, nickel, manganese, arsenic, antimony, bismuth, barium, cadmium or chromium ion, and the microbicide can be used as antimicrobial

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compositions which comprise the microbicide mixed with various binders or as antimicrobial shaped products which comprise the microbicide supported on carriers such as fibers, films, papers, and plastics (col. 1, ln. 4-14). Silver is the especially preferred metal from the points of stability and antimicrobial activity (col. 3, ln. 1-2). Specific examples of phosphate antimicrobials include (col. 3, ln. 14-53; and Table 5):



Sugiura et al. teach preparation of the above microbicides wherein after completion of washing with water, the residue was subjected to classification using a screen to collect fine particles of 1.0 μm or less (col. 10, ln. 31-34). The microbicide can be used in various forms such as powder-containing films (col. 5, ln. 21-35), wherein the films include food-packaging films and medical films (col. 5, ln. 44-45). Evaluation test 1 teaches adding 2 parts by weight microbicide to 100 parts by weight polyethylene terephthalate in a solvent, injection molding at 270 $^{\circ}\text{C}$ to make a product (col. 8, ln. 5-12). Sugiura et al. further teach fine powders comprising silver wherein the average particle size is 1.0 or 1.1 μm (col. 13, ln. 6-14). Sugiura et al. claim a method of

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inhibiting the growth of microorganisms on a surface comprising coating or impregnating said surface with an antimicrobially effective amount of the microbicide (claim 6).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to incorporate the anti-microbial phosphate containing an anti-microbial metal ion according to Sugiura et al. into the anti-microbial films according to Konagaya et al. One of ordinary skill in the art would have a reasonable expectation of success because Sugiura et al. teach incorporation of the phosphate containing silver into films wherein the resulting films are antimicrobial.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on pages 9-10 that examples of coating compositions which are laminated onto the substrate as taught by Konagaya et al. are not capable of providing the instantly claimed heat-seal strength and/or barrier properties. However, the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate

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affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, *inoperability of the prior art*, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP 716.01(c)(II).

Also, as noted by applicants, Konagaya et al. teach as one preferred embodiment an antibacterial composition comprising an antibacterial agent and a hydrophilic substance wherein the composition may be laminated on a substrate, such as films. Konagaya et al. teach that a specific example of the hydrophilic substance includes polyvinyl alcohol and polyester (pg. 7, ln. 5 and claim 11), which applicants claim as two of the polymers suitable for forming their coating layer.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616